

Gel Bleed Testing and GPC Analysis

6.0 CONCLUSION

Gravimetric results in this report measuring total normalized weight gain over eight weeks of 0.0152 g/cm² for Style 40 (smooth) test specimens, and 0.0048 g/cm² for Style 110 textured test specimens were comparable with gravimetric results of 0.0130 g/cm² for Style 40, and 0.0042 g/cm² for Style 110 (textured) test specimens.

Chemical characterization by Gel Permeation Chromatography demonstrated that the molecular weight of device bleed was lower than that of hexane extractable components of the device gel. These results are consistent with the results of testing presented in which demonstrated that lower molecular weight components of the gel are preferentially soluble in the device shell.

Since the components of bleed must diffuse from the gel through the shell, the fact that lower molecular weight components of the gel are preferential soluble in the shell explains why the molecular weight of gel bleed is lower than extracts of device gel.